

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12521330 <i>JEH/RBR</i>	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001423	International filing date (day/month/year) 15 October 2004	Priority date (day/month/year) 15 October 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C12N 15/48, A61K 39/21		
Applicant VIRAX DEVELOPMENT PTY LTD et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 9 sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 15 August 2005	Date of completion of the report 23 August 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT, 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ALISTAIR BESTOW Telephone No. (02) 6283 2450

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001423

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1 - 45** as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* **46 - 54** received by this Authority on **15 August 2005** with the letter of 15 August 2005.

pages* received by this Authority on with the letter of

☒ the drawings:

pages **1/28 - 28/28** as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001423

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 – 62.	YES
	Claims	NO
Inventive step (IS)	Claims 1 – 62.	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 – 62.	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Citations

D1 WO 2000/028003 A1

D2 KENT, S. J., et. al. Vaccine 18:2250-6.

D3 WO 2004/058278 A1

D4 Chemical Abstracts 141:151863.

Novelty (N) and Inventive Step (IS)

The citations may disclose the treatment of retroviral infection by administering certain vectors to induce, enhance an immune response, but none of the citations D1 – D4 discloses or suggests methods of reducing or alleviating one or more side effects of anti-retroviral drug therapy in the manner presently claimed. Neither do the citations disclose or suggest certain vectors when used during interrupted antiviral drug therapy to prevent, reduce or delay viral rebound; or certain vectors when used to reduce or alleviate one or more side effects of antiviral drug therapy. Therefore the claimed matter is both novel and inventive.

Industrial Applicability (IA)

The claimed matter appears to be industrially applicable.

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001423

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. <u>Patent No.</u>	Publication date <u>(day/month/year)</u>	Filing date <u>(day/month/year)</u>	Priority date (valid claim) <u>(day/month/year)</u>
P,X WO 2004/058278	15 July 2004	15 December 2003	16 December 2002

The citation discloses the preparation of poxvirus vectors (particularly vaccinia) expressing IL-15 and viral peptides (particularly HIV peptides). See example 2 and Figure 5. The citation however does not disclose methods of reducing or alleviating one or more side effects of anti-retroviral drug therapy in the manner presently claimed.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☒ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed
- ☐ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purposes of search and/or examination
- ☐ received by this Authority as an amendment* on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."